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TITLE: Perspiration Thresholds and Secure Suspension for Lower Limb Amputees in Demanding Environments

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14. ABSTRACT

The objective of this project is to provide active lower limb amputees who work in demanding environments with a prosthesis and suspension that remains secure despite profuse residual limb perspiration. The specific aims are to: (1) Identify the environment and perspiration thresholds at which the current standard-of-care prosthesis fails to provide a secure suspension, and (2) Compare the performance of the current standard-of-care prosthesis with an innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration.

Through the current reporting period, we have enrolled 10 individuals with lower limb amputation into an IRB-approved protocol to walk on a treadmill for up to 30-minutes in a chamber at 20, 30, and 35 deg C at 50% relative humidity. The cross-over experimental design randomizes the order of the study prostheses. The interim results suggest that despite greater perspiration while wearing the dynamic air exchange prosthesis, it may provide greater adherence (less slippage) in demanding conditions. Subject recruitment is on-going.

15. SUBJECT TERMS

Lower extremity amputee, transtibial, artificial limb, prosthesis, skin temperature, perspiration

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1. INTRODUCTION:

Lower limb amputees often complain about uncomfortable residual limb skin temperatures and the accumulation of perspiration inside their prostheses that sometimes leads to an insecure prosthetic suspension (i.e., the prosthesis falls off during vigorous activity). The purpose of this project is to provide active lower limb amputees who work in demanding environments with a prosthesis and suspension that remains secure despite profuse residual limb perspiration. The scope of this research includes: (1) identifying the environment and perspiration thresholds at which the current standard-of-care prosthesis fails to provide a secure suspension, and (2) comparing the performance of the current standard-of-care prosthesis with an innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration. The work to achieve these aims includes: (1) fabricating, assembling, and fitting standard-of-care and dynamic air exchange prostheses to volunteer lower limb amputees, and (2) conducting a human subject experiment with subjects walking on a treadmill in at different environment temperatures. The dynamic air exchange prosthesis is expected to significantly surpass the thresholds at which the standard-of-care fails.

2. KEYWORDS:

Lower extremity amputee, transtibial, artificial limb, prosthesis, skin temperature, perspiration

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The statement of work (SOW), approved revision dated 14 September 2016, for this project includes two major tasks:

Major Task 1. Fabricate dynamic air exchange prosthetic components at the Arusha Control site. Activities associated with this task include: purchasing supplies, receiving residual limb casts from the VA Puget Sound Health Care System (VAPSHCS) site, fabricating custom, moisture-wicking textile sock with a proximal elastomeric seal, fabricating prosthetic sockets, fabricating electronic components, fabricating housings, performing bench and quality assurance testing, and shipping components to the VAPSHCS site. The milestones for this task are shown in Table 1.

Table 1: Major task 1 milestones.

Task	**Timeline (months)**
Milestone 1.1: Deliver unit (1)	3
Quarterly Recurring Milestone 1.2+: Deliver units (as needed)	6, 9, …, 30, 33

Major Task 2. Conduct a human subject experiment at the VAPSHCS site to compare the performance of the study prostheses. A human subject experiment with transtibial amputees (n=25) will be conducted involving two study prostheses (standard-of-care v. dynamic air exchange) and their performance in three environmental conditions (20, 30, and 35 °C and 50% relative humidity). Subjects will walk on a treadmill in an environmental chamber and the time until loss of prosthetic suspension and the amount of perspiration accumulated/expelled will be measured. Hypotheses comparing the performance of the two study prostheses will be tested, the results documented and disseminated to program officials, clinicians, and amputees.

The components of the innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration will be fabricated at the Arusha Control site. Final assembly of prosthetic components and fitting of the prosthetic assemblies will occur at the VAPSHCS site.

Activities associated with this task include: obtaining and maintaining regulatory approvals, recruiting subjects, casting residual limbs, shipping casts to the Arusha Control site, receiving components from the Arusha Controls site, assembling final prostheses, conducting human subject tests, securing test data, analyzing test data, performing hypothesis tests, and documenting results.

The milestones for this task are shown in Table 2.

Table 2: Major task 2 milestones.

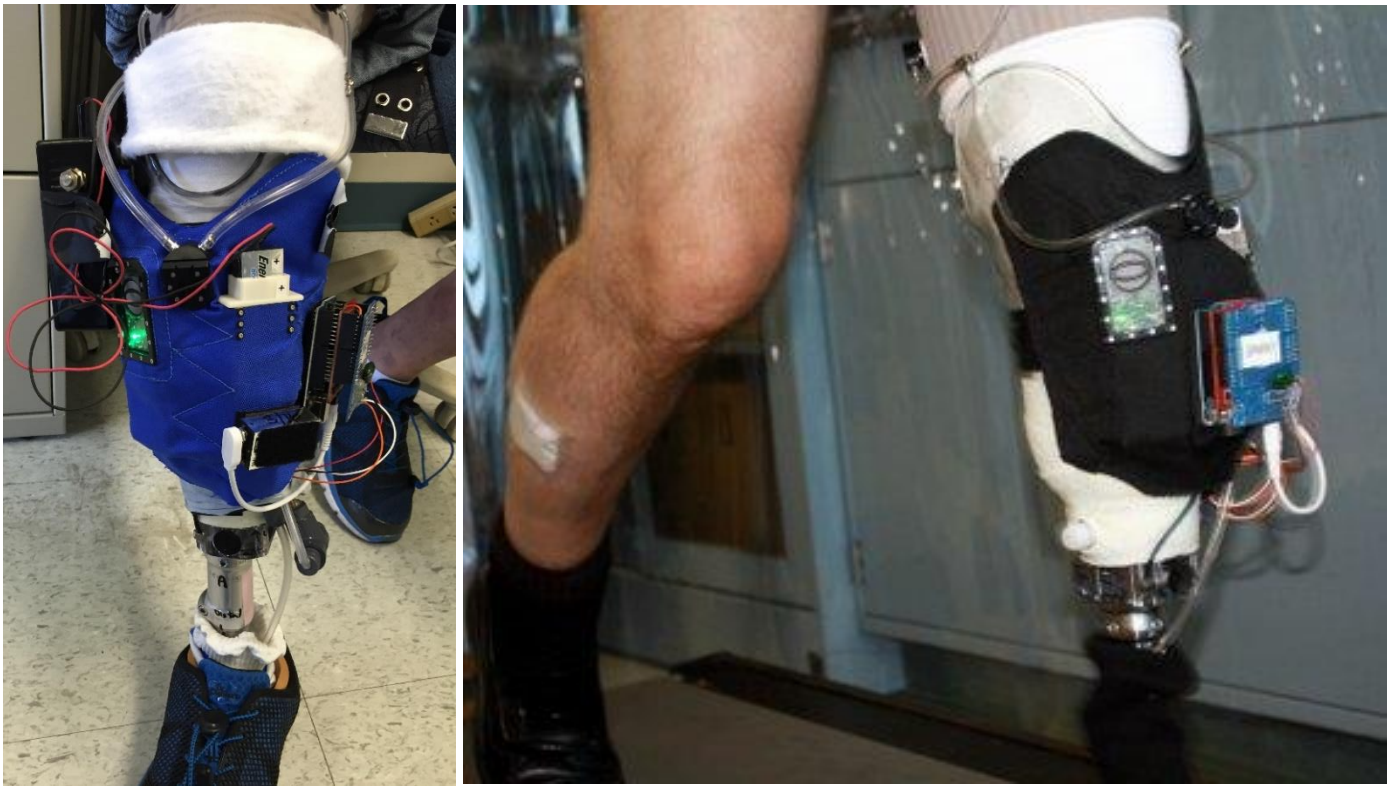
Task	**Timeline (months)**
Subtask 2.1: Obtain approval from all governing Institutional Review Boards (HRPO/IRB)	1-3
Subtask 2.2: Commission climate chamber	1-2
Subtask 2.3: Conduct human subject experiment	3-33
Milestone 2.1: Recruit subject (1)	3
Milestone 2.2: Recruit subjects (4)	6
Milestone 2.3: Recruit subjects (4)	9
Subtask 2.4: Analyze preliminary data & report results	9-12
Quarterly Recurring Milestone 2.4+: Recruit subjects (as available)	12, 15, …, 30, 33
Subtask 2.5: Analyze data & report results	33-36

What was accomplished under these goals?

Major Task 1. The work during this reporting period included continued fabrication of components to be used in assembling the study prostheses for our human subject experiments. We have fabricated components for eleven complete prostheses (see Figures 1b and 2) and delivered them to the VA site for human subject testing. We have also fabricated additional components (see Figure 1a) which are ready to be assembled as needed. These components include: the proximal port snap housings, molded pump housings, distal liner pin with wrench flats for ease of installation, electronic circuit boards, on-board control switch assemblies, 9-volt battery holder, vacuum manifolds, hose barb O-ring installations, custom socks, and system packaging using a fabric harness. We have also refined our prosthetist fitting aids and instructions including charts to assist with liner and sock sizing and trim lines.

Major Task 2. During the current reporting period, we have maintained approvals from our governing institutional review boards (HRPO and VA IRB), continued recruiting and enrolling participants, and conducted a preliminary analysis of our study data.

Subtask 2.1: Obtain (*and maintain*) approval from all governing Institutional Review Boards (HRPO/IRB). Our use of human subjects has undergone continuing review and we have maintained our approvals. Please see Appendix A for specific details.



(a) (b)

Figure 1: (a) Complete dynamic air exchange prosthesis fit to subject. (b) Lower limb amputee wearing the dynamic air exchange prosthesis while walking on the treadmill in the climate chamber.

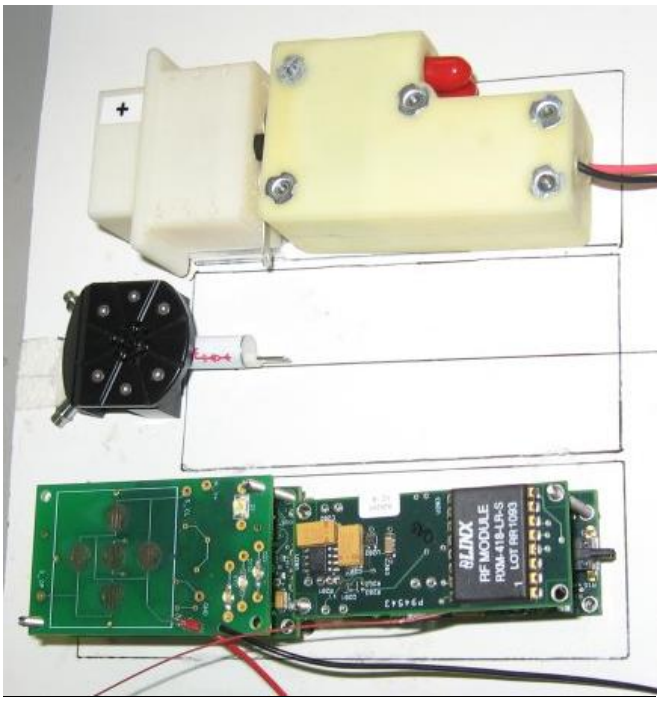


Figure 2: Image of the housing, port manifold, and electronic circuit boards.

Subtask 2.2: Commission climate chamber. This subtask was completed during the previous reporting period.

Subtask 2.3: Conduct human subject experiments. We have continued to conduct human subject experiments during the current reporting period (see Table 3) and have expanded our recruitment methods. In addition to posting flyers at IRB-approved kiosks, screening VAPSHCS clinical lists and the VA Computerized Patient Record System (CPRS) for appropriate candidates, we are also using our VA IRB-approved Subject Registry (#00433). During the current reporting period, we have used mass media advertising to recruit new individuals into the Subject Registry which we then use to recruit for this study. To further facilitate recruiting, we are leveraging VA funding to hire an additional person to perform this task (for this study and others). We anticipate this position to be filled during the first quarter of FY2017.

Table 3: Human subject quarterly and cumulative enrollment over the period (two-year grant plus approved one-year no-cost extension). All human subject procedures are performed at site 1.

Enrollment	**Year One**				**Year Two**				**Year Three**				**Total**
	Q1	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**Q11**	**Q12**	
Quarterly Actual/Target	0/0	0/1	3/2	2/2	3/2	1/2	1/2	0/2	/4	/4	/4	/0	**/25**
Cumulative Actual/Target	**0/0**	**0/1**	**3/3**	**5/5**	**8/7**	**9/9**	**10/ 11**	**10/ 13**	**/17**	**/21**	**/25**	**/25**	**/25**

Subtask 2.4: Analyze preliminary data & report results. Experimental data was collected during the current reporting period. These data collections are ongoing. We have conducted a preliminary analysis of our first five participants (49±12 yo, 93±14 kg, 1.82±0.06 m, 19±15 years post-amputation, n=4 trauma, n=1 secondary to infection). All were fit a modified patellar tendon bearing socket and two study suspensions: (1) a distal PIN locking liner and (2) the dynamic air exchange (DAE) system that allows expulsion of any accumulated perspiration. Subjects were randomized to study prosthesis and asked to walk at their self-selected speed on a treadmill in an environmental chamber at 50% relative humidity (RH) and 20, 30, and 35° C, presented in random order. A 26 cm^2 absorbent patch was also placed on the lateral calf of the contralateral limb. While in the chamber, subjects rested while seated for 30 min, then walked for 30 min or until they lost confidence in the security of their prosthetic suspension, and then rested outside the chamber (~50% RH, 20° C) while seated for 30 min. Perspiration amounts were measured by tare weight (g) at the end of the protocol. Liner slippage (n=2) was measured by marking the skin at the proximal border of the liner prior to the protocol and measuring the distance (mm) between the mark and the liner at the end of the protocol. A linear mixed model was used to determine if differences in contralateral limb perspiration were statistically significant ($p<0.05$). Other metrics were not statistically analyzed.

No subject lost confidence in the security of their suspension; all walked for 30 min in all conditions. One subject experienced pistoning at 30 and 35° C while wearing the PIN, but was confident to continue the protocol. Liner slippage (n=2) was greater for the DAE than PIN at 20° C but greater for PIN than DAE at 35° C (see Table 4). The DAE accumulated more perspiration (see Table 5) and resulted in more total perspiration (accumulated + expelled) than PIN at each temperature. Individual results were highly variable as indicated by the large standard deviations. The DAE prosthesis expelled 51, 11, and 20 percent of the total perspiration at 20, 30, and 35° C, respectively. No difference in contralateral limb perspiration was observed across temperature ($p>0.05$.

Table 4: Liner slippage (mean ± standard deviation) from two subjects (mm).

Suspension system	20° C	30° C	35° C
PIN locking liner	5±5	17±19	46±34
Dynamic Air Exchange	21±29	17±23	33±43

Table 5: PIN locking liner and Dynamic Air Exchange perspiration (mean ± standard deviation) from five subjects (g).

	20° C	30° C	35° C
Accumulated in PIN locking liner	0.0±0.1	0.6±0.8	1.3±1.8
Accumulated in Dynamic Air Exchange	0.3±1.0	2.0±2.8	4.1±5.9
Expelled by Dynamic Air Exchange	0.3±0.2	0.3±0.2	1.0±1.4
Contralateral limb PIN locking liner	0.2±0.1	0.5±0.5	0.5±0.3
Contralateral limb Dynamic Air Exchange	0.5±0.9	0.3±0.2	0.5±0.4

Even at 35° C, all subjects walked for 30 min without losing adherence, suggesting a more demanding protocol is needed to identify loss of suspension thresholds. The DAE liner slipped more than PIN at 20° C, but the PIN slipped more than DAE at 35° C, suggesting the heavier DAE may be beneficial in more demanding conditions. The DAE expelled a portion of the accumulated perspiration at each temperature, but subjects perspired more while wearing it compared to the PIN. These interim results suggest that despite greater perspiration while wearing the DAE, it may provide greater adherence (less slippage) in demanding conditions. Enrolling additional subjects is warranted.

This subtask also includes performing a statistical analysis to determine the number of subjects required to accurately test the study hypotheses. This task remains incomplete until two additional subjects have been recruited and complete all study procedures.

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

During the next year (approved no cost-extension period), we plan to continue fabricating prosthesis components, assemble complete prostheses, enroll lower limb amputee participants, and conduct human subject tests using our approved protocol.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

There have been no significant changes in the project or its direction.

Actual or anticipated problems or delays and actions or plans to resolve them

At the beginning of the fourth quarter of FY2016, our VA-funded research prosthetist, Mr. Daniel Daley, resigned to take a position in private practice. The role of the research prosthetist is to order prosthetic supplies, assemble prosthetic systems, fit prostheses to test subjects, perform adjustments and alignments, participate in research team meetings to discuss findings, assist in formulating study conclusions, and assist in result documentation. During the fourth quarter of FY2016, we received the occasional assistance of a VA-funded prosthetist, Mr. Wayne Biggs, L/CPO, to perform these tasks. At the beginning of the first quarter of FY2017, Mr. George Eli Kaufman, also a VA-funded prosthetist, will take over this role. We anticipate no delays related to the delivery of prosthetic services.

Changes that had a significant impact on expenditures

Nothing to report.

6. PRODUCTS

Publications, conference papers, and presentations

During the current reporting period, the PI submitted an abstract describing the preliminary results of this research for consideration to be included in the American Academy of Orthotists & Prosthetists 43rd Annual Meeting & Scientific Symposium, to be held on March 1-4, 2017 in Chicago, IL. This abstract was accepted for a podium presentation.

Klute GK, Berge JS, King C. “Perspiration and secure suspension for lower limb amputees in demanding environments.” American Academy of Orthotists & Prosthetists, 43rd Academy Annual Meeting & Scientific Symposium, March 1-4, 2017.

Journal publications

During the current reporting period, the PI published a manuscript describing the dynamic air exchange prosthesis and its performance in a similar rest-walk-rest protocol with lower limb amputees (n=5) while wearing thermally-insulative garments in a laboratory environment (~30% relative humidity and 20° C). The results reveal the DAE prosthesis expelled more than a third of the total perspiration, suggesting it may enable longer uninterrupted periods of perspiration-inducing activity.

Klute GK, Bates KJ, Berge JS, Biggs W, King C. Prosthesis management of residual-limb perspiration with subatmospheric vacuum pressure. J Rehabil Res Dev, 2016;53(6). 10.1682/JRRD.2015.06.0121

Books or other non-periodical, one-time publications

Nothing to report.

Other publications, conference papers, and presentations

During the current reporting period, the PI presented a project summary with results to DOD personnel and selected invitees at Ft. Detrick on 27Sep2016.

Klute, GK. "Perspiration thresholds and secure suspension for lower limb amputees in demanding environments." U. S. Army Medical Research and Material Command, Clinical and Rehabilitative Medicine Research Program, Socket Technology and Related Limb Health In-Progress Review, Ft. Detrick MD, September 27, 2016.

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	*Glenn K. Klute, PhD*
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	*GKLUTE*
Nearest person month worked:	*1*
Contribution to Project:	*No changes.*
Funding Support:	*VA Research Career Scientist (A9248-S)* *Dept. of Veterans Affairs, Rehabilitation R&D Service*

	This award supports Dr. Klute's research (salary only) to improve the quality of life and functional status of Veteran lower limb amputees.

Name:	*Charles King, CPO*
Project Role:	*Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*3*
Contribution to Project:	*No changes.*
Funding Support:	*None to report.*

Name:	*Jocelyn S. Berge, MSE*
Project Role:	*Investigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*12*
Contribution to Project:	*No changes.*
Funding Support:	*None to report.*

Name:	*Daniel M. Daley*
Project Role:	*Research prosthetist*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*2*
Contribution to Project:	*Prosthesis final assembly, fit, and alignment.*
Funding Support:	*Center of Excellence for Limb Loss Prevention & Prosthetic Engineering (A9243C), Dept. of Veterans Affairs, Rehabilitation R&D Service*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last

reporting period?

The PI had one grant end during the current reporting period. There was no change in the PI's level of effort.

W81XWH-09-2-0144 21 September 2009 – 20 September 2016
PIs: Glenn K. Klute, PhD, "Prosthetic knee-ankle-foot system with biomechatronic sensing, control and power generation"

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS:

Please see Department of Defense Quad Chart in Appendix B.

Budget Expenditure to Date:
FY16 Projected Expenditure: $333,225
FY16 Estimated Expenditure: ($266,963)

9. APPENDICES:

This annual report includes two appendices:

A. Human subjects enrollment table.
B. Department of Defense Quad Chart (updated October 28, 2016).

Appendix A: Human Subjects Enrollment Table

Protocol: A-18175
Title: Perspiration Thresholds and Secure Suspension for Lower Limb Amputees in Demanding Environments

Continuation documents for protocol A-18175 was reviewed by the US Army Medical Research and Materiel Command's (USAMRMC) Office of Research Protections, Human Research Protection Office (HRPO) on 10 June 2016 and found to be in compliance with Federal, Dept. of Defense, and US Army human subjects protection requirements. The study is currently approved to enroll 40 subjects.

The VA Puget Sound Healthcare System Institutional Review Board (IRB) approved continuation of the protocol (VA #00695) on 6 April 2016. Approval to enroll no more than 40 subjects in this moderate risk study will expire on 5 April 2017.

Table A: Human subject cumulative enrollment (actual and target) over the two-year plus one-year no cost extension period of performance. Actual enrollment includes participants since the beginning of the project (September 30, 2014) through the end of year two (September 29, 2016). All human subject procedures were performed at site 1.

Patient Population	**Year One Actual/Target**	**Year Two Actual/Target**	**Year Three Actual/Target**
Transtibial Amputees	5 / 5	10 / 13	/ 25

Appendix B: Department of Defense Quad Chart (updated 28 October 2016)

Perspiration Thresholds & Secure Suspension for Lower Limb Amputees in Demanding Environments

Log Number OR130260, Award Number W81XWH-14-1-0188

PI: Glenn K. Klute, PhD **Org:** Seattle Institute for Biomedical and Clinical Research **Award Amount:** $674,942

Objective

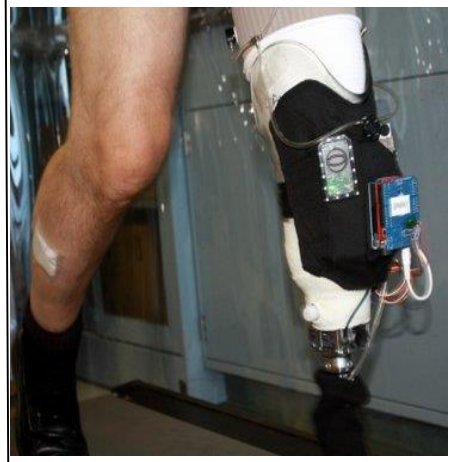
Provide active lower limb amputees who work in demanding environments with a prosthesis that remains secure despite profuse perspiration.

Study Aims

- Identify environment & perspiration thresholds at which the current standard-of-care prosthesis fails to provide secure suspension.
- Compare the performance of the current standard-of-care prosthesis with an innovative prosthesis that expels perspiration.

Approach

Conduct within-subject experiment with transtibial amputees (n=25) walking on a treadmill in three environmental conditions (20, 30, and 35 °C and 50% relative humidity) wearing standard-of-care and innovative prostheses.



Innovative Prosthesis Design

A battery-powered pump creates a small pressure differential (vacuum) between the proximal and distal regions of the donned prosthesis. This pressure differential, when carefully controlled, causes air flow inside the prosthesis, providing a means for expelling perspiration into an exterior chamber while maintaining a secure suspension.

Accomplishments: Ten transtibial amputees have been enrolled to date & 20 standard-of-care and innovative prostheses have been fabricated & fit. Five amputees have completed the treadmill protocol at 20, 30, and 35 °C.

Timeline and Cost

Activity	FY15	FY16	FY17
Maintain IRB approvals & operate climate chamber			
Recruit participants			
Fabricate prosthetic components			
Conduct human subject tests			
Analyze & report results			
Estimated Budget ($K)	$342	$267	$66

Updated: 28Oct2016

FY16 Activities

- ☑ Maintain HRPO/IRB approvals
- ☑ Fabricate prosthetic components
- ☑ Enroll lower limb amputee participants (n=10 to date)
- ☑ Conduct human subject experiments
- ☐ Perform preliminary analysis & report results

FY17 Goals & Activities

- ☐ Maintain regulatory approvals
- ☐ Fabricate prostheses
- ☐ Conduct human subject experiments
- ☐ Perform analysis & report results

Budget Expenditure to Date

FY16 Projected Expenditure: $333,225

FY16 Estimated Expenditure: ($266,963)